

REMARKS

Applicants thank the examiner for withdrawing the prior rejection under 35 U.S.C. § 251.

This Amendment is accompanied by the following exhibits:

- Exhibit A: Ex parte Spitz, slip op. at 5 (BPAI 9/15/2000) (Appeal No. 1997-2378)
- Exhibit B: Declaration of Dr. Steven J. Saul under 37 C.F.R. § 1.132 with Exhibits 1-10
- Exhibit 1: Curriculum vitae of Dr. Steven J. Saul
- Exhibit 2: Stanley, P.E., *Extraction of Adenosine Triphosphate from Microbial and Somatic Cells, Methods in Enzymology*, 133:14-22 (1986)
- Exhibit 3: Andreotti et al., WO 92/20781, November 26, 1992
- Exhibit 4: Wood, US Patent No. 5,283,179, 1994
- Exhibit 5: Optimization of the Firefly Luciferase Assay for ATP (Webster, J.J., and Leach, F.R., *Jour. Applied Biochemistry*, 2:469-479, 1980)
- Exhibit 6: Effect of Solvents on the Catalytic Activity of Firefly Luciferase (Kricka, L.J. et al., *Archives of Biochemistry and Biophysics*, 217(2), 1982)
- Exhibit 7: U.S. Patent No. 5,004,684, Simpson et al, 1991
- Exhibit 8: US Patent No. 4,303,752, Kolehmainen et al., 1981
- Exhibit 9: Denville Scientific Inc., *Research Products Catalog 1991*, pages 1, 2, 15
- Exhibit 10: Denville Scientific Inc., *Research Products Catalog*, 1995, pages 1, 2, 16

Supplemental Reissue Declaration

Pursuant to 37 CFR 1.175, applicants enclose a Supplemental Reissue Application Declaration By All Inventors, updating and verifying that all errors being corrected arose without any deceptive intent (submitted herewith unsigned; a signed copy of the Supplemental Reissue Application Declaration By All Inventors will be provided by subsequent transmittal).

**Status of Claims and Support for Claim Changes pursuant to
37 CFR 1.173**

Claims 1-26 are pending. By this amendment, claims 3, 11, 13, 16, and 20 have been canceled, claims 1, 4, 5, 7, 10, 12, 14, 17, 19, 21, and 24 are amended, and claims 27-45 are new.

Claim 1 (original, pending, twice amended) is amended by (1) deleting “or alkaline phosphatase (AP)” from the preamble and from the phrase at (c)(i), (2) deleting “a reaction stopping solution having a pH of 8 to 11”, and (3) deleting “or phosphatase substrate”, which amendments are without prejudice in view of the subject matter of new claim 27 and claims depending therefrom.

Claim 2 (original, pending).

Claim 3 (original, cancelled) is cancelled without disclaimer as to the breadth of embodiments encompassed by claim 1, and without prejudice as to new claim 29.

Claim 4 (original, pending, twice amended) is amended in response to the examiner’s suggestion that claim 4 would be allowable if rewritten in independent form, by incorporating the limitations of the claims from which it depends. *Office action, page 17.*

Claim 5 (original, pending, twice amended) is amended herein by deleting, from the listed reagent compositions, “or alkaline phosphatase (AP)”, “a reaction stopping solution having a pH of 8 to 11” and “or phosphatase substrate”, which amendment is without prejudice in view of new claim 31.

Claim 6 (original, pending, previously amended).

Claim 7 (original, pending, amended) is amended, solely for clarity, by replacing ‘includes’ with – further comprises--.

Claim 8 (original, pending).

Claim 9 (original, pending).

Claim 10 (original, pending, third time amended) is amended herein by deleting from the listed reagent compositions, “or alkaline phosphatase (AP)” and “a reaction stopping solution having a pH of 8 to 11”.

Claim 11 (original, cancelled) is cancelled without disclaimer as to the breadth of embodiments encompassed by claim 1, and without prejudice as to any alternative grounds for the patentability of other claims reciting the limitation “threadable means to move the probe spirally and longitudinally . . .”.

Claim 12 (original, pending, twice amended) is amended herein by deleting, from the listed reagent compositions, “or alkaline phosphatase (AP)”, “a reaction stopping solution having a pH of 8 to 11” and “or phosphatase substrate”, which amendment is without prejudice in view of new claim 37.

Claim 13 (original, pending) is cancelled without disclaimer as to the breadth of embodiments encompassed by claim 1, and without prejudice as to new claim 38.

Claim 14 (original, pending, twice amended) is amended by deleting recitals of “or alkaline phosphatase (AP)” and “by color”, which amendment is without prejudice in view of new claim 39.

Claim 15 (original, pending).

Claim 16 (original, cancelled) is cancelled without disclaimer as to the breadth of embodiments encompassed by claim 14, and without prejudice as to new claim 41.

Claim 17 (original, amended) is amended by replacing “removedly, threadably” with “means for detachably securing.” This amendment is made solely for the purpose of taking

advantage of the *in haec verba* support in the '081 provisional at page 1, line 26, and in figure 3, and is not intended to disclaim any subject matter that would be understood by the ordinary artisan to be encompassed within such disclosure.

Claim 18 (original, pending).

Claim 19 (original, pending, twice amended) is amended to restore the comma prior to the phrase "is at the bottom end", which comma was inadvertently included within brackets of the preliminary amendment filed 12/6/2001.

Claim 20 (original, cancelled) is cancelled without prejudice in view of new claim 44.

Claim 21 (original, pending, third time amended) is amended to include "a test sample" in the preamble for the purpose of creating antecedent basis for "test sample" in 21(c). A further amendment to claim 21, replacing "threads for threadable attachment of" with "means for detachably securing," finds support in the '081 provisional at page 1, line 26, and in figure 3. This amendment is made solely for the purpose of taking advantage of *in hac verba* support, and is not intended to disclaim any subject matter that would be understood by the ordinary artisan to be encompassed within this disclosure.

Claim 22 (original, pending).

Claim 23 (original, pending, previously amended).

Claim 24 (pending, amended) is amended to depend from claim 19 instead of claim 14.

Claim 25 (pending).

Claim 26 (pending).

Claims 27-44 (new) are directed to unit dose reagent chambers for use in a test apparatus for the detection of alkaline phosphatase (AP), and are supported by original claims 1-26.

Claims 27-44 have been drafted to mirror the language of previously examined claims 1-26, so that no further examination should be necessitated by applicant's amendment. Support for the subject matter of claims 27-44 was stated by examiner in the instant office action to be found in provisional application 60/007,585, filed 27 Nov. 1995.

Applicant notes that the examiner has already conducted prior art searches with respect to the subject matter set forth in claims 27-44; and that any issues pertaining to the statutory requirements of 35 U.S.C. § 112 have been dealt with in prior office actions in connection with the language and format of former claims 1-26. Accordingly, the addition of new claims 27-44 should not raise new issues for examination.

Claim 45 (new) is directed to a test unit having threads for attaching and detaching the test unit to a test apparatus, and is thus of comparable scope to claim 21 prior to its current amendment.

Priority Determination

The Office has taken the position that, although claims 1-26 are entitled to the effective filing date of U.S. provisional application no. 60/007,585, filed November 27, 1995, claims 1-26 would not be entitled to the effective filing date of U.S. provisional application no. 60/001,081, filed July 12, 1995 ("the '081 provisional"), on the grounds that the '081 provisional allegedly lacks adequate support for certain recited claim terms. Applicant respectfully traverses this position.

Claims 1-26 as amended are fully supported by the '081 provisional, and thus entitled to an effective filing date of July 12, 1995. The specific issues raised in the Office Action are addressed below, with reference to the specification and drawings of the '081 provisional as

originally filed July 12, 1995, and with reference to the accompanying Saul Declaration and exhibits thereto.

A. Alkaline Phosphatase

For the purpose of narrowing the issues in dispute, claims 1, 5, 10, 12, 14, and 21 have been amended to exclude the subject matter that relates solely to devices for detection by means of an alkaline phosphatase (AP) assay. Accordingly, in claims 1, 5, 10, 12, 14, and 21 as amended, the term “alkaline phosphatase (AP)” has been deleted from each respective preamble, the phrase “detergent-containing buffered solution to release adenosine triphosphate (ATP) or alkaline phosphatase (AP)” has been amended to “detergent-containing buffered solution to release adenosine triphosphate (ATP)”, and the terms “a reaction stopping solution having a pH of 8 to 11” and “phosphatase substrate” have been deleted.

B. The specification and drawings of the ‘081 provisional in combination with the Saul Declaration and the articles submitted therewith establish that the ‘081 provisional, as originally filed, provides the necessary descriptive support for the limitations of the amended claims.

The specification and drawings of the ‘081 provisional, in combination with the Saul Declaration and the articles submitted therewith establish, that the ‘081 provisional as originally filed provides the necessary descriptive support for the limitations of the amended claims. Ex parte Spitz, *slip op.* (BPAI 9/15/2000) (Appeal No. 1997-2378) (“We agree with the examiner that the specification alone fails to provide descriptive support for the language at issue . . . Nevertheless, the specification in combination with the Kang article and the declaration of Brun and Duranel establish that the specification, as originally filed, provides the necessary descriptive support.”). (A copy of Ex parte Spitz is attached as Exhibit A hereto.)

Specifically, the Examiner has raised the priority issue with respect to the following limitations:

(a) whether the '081 provisional provides an adequate written description of "buffered solution to release adenosine triphosphate (ATP) from the test sample" (claims 14-15, 17-19, and 24);

(b) the '081 provisional provides an adequate written description of "detergent-containing buffered solution to release adenosine triphosphate (ATP)" (claims 1, 2, 5-13)

(c) the '081 provisional provides an adequate written description of "transparent" (claims 7, 14, and 21); and

(d) the '081 provisional provides an adequate written description of "the one end having threads for attachment of the test unit to the test apparatus" (claim 21).

The test for determining compliance with the written description requirement does not

require literal support in the specification for the claim language, but rather that the disclosure as originally filed, including the original drawings, would reasonably have conveyed to the artisan that the inventor had possession of the later claimed subject matter. Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563, 19 U.S.P.Q.2d 1111, 1116 (Fed.Cir., 1991). Accordingly, the Federal Circuit Court of Appeals ("Federal Circuit") has held that the subject matter of the claim need not be described identically or literally for the application to satisfy the written description requirement. Id.; Kennecott Corp. v. Kyocera Int'l Inc., 835 F.2d 1419, 1423, 5 USPQ2d 1194, 1198 (Fed. Cir. 1987) ("In the case at bar the additional description was not of a new use, but of the existing physical structure of the product."). Moreover, an application need not describe the claim limitations in greater detail than the invention warrants; it is only necessary that the description be sufficiently clear that persons skilled in the art would have recognized that the applicant made the invention having those limitations. Behr et al. v. Talbott et al., 27 U.S.P.Q.2d 1401, 1407 (BPAI, 1992).

The Board of Patent Appeals and Interferences has followed such guidance and precedent of the Federal Circuit, by repeatedly holding that written description support can be either express or inherent support. Behr et al., 27 U.S.P.Q.2d at 1407 (“The written description requirement can be satisfied by showing that the disclosed subject matter, when given its necessary and only reasonable construction, inherently satisfies the limitation in question.”); Spitz, *slip op.* at 5.

(a) *It is agreed that express disclosure is found in the ‘081 provisional ‘lysis solution’, ‘ATP stabilizer’ and “buffer optimized for luciferin-luciferase reaction’, and no issue remains as to these terms.*

The Examiner has made a finding that the ‘081 provisional provides express disclosure of “microbial lysis solution”, “ATP stabilizer,” and “buffer optimized for luciferin-luciferase reaction.” Office Action, page 3. The meanings of terms such as “microbial lysis solution” and “buffer optimized for luciferin-luciferase reaction” were conventional and commonly understood by those of ordinary skill in the art in 1995, with such meanings reflected in the literature of the time. Saul Declaration, § 5.

(b) *The ‘081 provisional provides adequate support for “buffered solution to release adenosine triphosphate (ATP) from the test sample”*

Referring to claims 14-20 and 24, the Examiner questions whether the ‘081 provisional application supports the phrase “reagent composition comprises a buffered solution to release adenosine triphosphate or alkaline phosphatase from the test sample.” Office Action, page 3. Reference to ‘alkaline phosphatase’ having been deleted from the claim language, the specific issue to be addressed is whether the ‘081 provisional provides support for “reagent composition

comprises a buffered solution to release adenosine triphosphate (ATP) from the test sample into the solution for subsequent reaction with the first reagent composition.”

(i) ‘solution to release adenosine triphosphate (ATP)’ from the test sample

Based on further review of positions taken by the Examiner within the Office Action itself, Applicant submits that this issue may actually be moot in view of the deletion of the ‘alkaline phosphatase’ limitations. In particular, the examiner’s use of the terms ‘extracting agent’, “releasing or extracting reagent”, “lysis solution”, “lysing reagent” and “lysis or extraction reagent” interchangeably. *See, Office Action*, at, e.g., page 8, lines 3, 4, 7, 11, and 13, respectively.

Those of ordinary skill in the art would have used such terms just as interchangeably. As demonstrated by the Declaration of Steven J. Saul, one skilled in the art in July of 1995 would have understood a ‘lysis solution’ to mean a solution for extracting or releasing ATP from cells. Saul Declaration, § 6. One skilled in the art would have further understood that a test sample taken from surfaces or from water and other biological fluids or foods for the purpose of detecting the presence of ATP would have invariably meant a test sample of a mixed population of cellular material. Saul Declaration, § 7; ‘081 provisional at page 1. Thus, applicant’s disclosed ‘lysis solution’ would have conveyed with reasonable clarity to the ordinary artisan a ‘solution to release adenosine triphosphate (ATP)’ from the test sample.’ Saul Declaration, §§ 6, 7.

(ii) 'buffered solution to release adenosine triphosphate (ATP)' from the test sample

The ordinary artisan would have understood just as clearly that such a solution would of necessity be buffered, using a buffer optimized for the luciferin-luciferase reaction. In his declaration, Dr. Saul testifies to the conventional understanding of those skilled in the art that the solution conditions employed for extracting ATP must be compatible with the reaction conditions required for the luciferin-luciferase assay. Saul Declaration, §§ 8-10. Such conventional understanding is reflected in the literary references offered by Dr. Saul, illustrating the conventional practice in 1995 of using buffered lysis solutions to extract ATP from cellular samples. Saul Declaration, § 8. By way of illustration, the Andreotti, Wood, and Simpson references (Exhibits 3, 4, and 7 to the Saul Declaration) summarize various then-known ATP releasing reagents, pointing out that ATP releasing reagents were commonly combined with buffers to adjust the pH. It was thus well known and established, even prior to Andreotti, that ATP release reagents were known to include a buffer composition. Saul Declaration, §§ 8, 10, and 13. More general guidance for optimizing buffer conditions for the luciferin-luciferase assay was available in an article by Webster et al. (Exhibit 5 to the Saul Declaration), setting forth affect of various buffers on luciferase activity. Saul Declaration, § 10.

Applicant therefore submits that the ordinary skilled artisan in 1995 would have necessarily understood the '081 provisional to describe a buffered solution to release adenosine triphosphate from the test sample into the solution for subsequent" detection by luciferin-luciferase assay.

(c) The '081 provisional provides adequate support for “detergent-containing buffered solution to release adenosine triphosphate (ATP) from the test sample into the solution for testing”

With reference to claims 1-13, the Examiner questions whether the '081 provisional provided adequate support for “detergent-containing buffered solution to release adenosine triphosphate (ATP) from the test sample into the solution for testing.” For the reasons articulated above, Applicant submits that the '081 provisional describes a “buffered solution to release adenosine triphosphate (ATP) from the test sample into the solution for testing”, and therefore confines the present argument to the term ‘detergent-containing.’

By 1995, one skilled in the art in 1995 would invariably have concluded that, of the methods available for releasing ATP from cells, a detergent-containing reagent would be a virtual necessity when detecting ATP with the firefly luciferase assay. Saul Declaration, §§ 11-14. Understanding of the importance of a detergent when extracting ATP from cells for detection by luciferase is particularly illustrated by the writing of Simpson et al. in U.S. Patent No. 5,004,684. Exhibit 7 to the Saul Declaration. In particular, Simpson uses a detergent-containing buffered solution to release ATP into the test solution for testing, making multiple references to extracting ATP from microorganisms using detergents in buffers that had been optimized for the luciferin-luciferase assay. Saul Declaration, § 13, *citing Simpson*, col. 3-4. Thus, by 1995 one skilled in the art would have understood that ample guidance was available for determining which detergents and in what concentrations.

Accordingly, applicant submits that one skilled in the art in July of 1995 would have understood from the disclosure of the '081 provisional that applicants were in possession of an invention that included an embodiment in which the reagent composition chosen was a

'detergent-containing buffered solution to release adenosine triphosphate (ATP)' from the test sample into the solution for testing.'

(d) The '081 provisional provides adequate support for the subject matter of a "transparent" test unit

The '081 provisional provides ample support for a test unit microtube that is 'transparent.' The examiner is directed to the drawings in, e.g., Figure 3 as filed in the '081 provisional, which illustrates an embodiment of a test unit microtube that has sides through which the observer can view the contents of the test unit microtube. Applicant submits that the recitation of 'transparent' in claims 14 and 21 is supported by the '081 provisional as filed, and that claims 14 and 21 are entitled to an effective filing date of July 12, 1995. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 U.S.P.Q.2d 1111, 1116 (Fed.Cir., 1991) ("drawings alone may provide a 'written description' of an invention as required by § 112").

(e) The '081 provisional provides adequate support for the subject matter "the one end having threads for attachment of the test unit to the test apparatus"

The examiner has taken the position with respect to claim 21 that the '081 provisional lacks adequate support for "the one end having threads for attachment of the test unit to the test apparatus."

The amendment of claim 21, replacing "threads for threadable attachment of" with "means for detachably securing," is made solely for the purpose of taking advantage of *in hac verba* support in the '081 provisional, and is not intended to disclaim any subject matter that would be understood by the ordinary artisan to be encompassed within this disclosure. *Ralston Purina Co.*, 227 USPQ at 180.

Although claim 21 (and also claim 8) no-longer recite such limitations, Applicant traverses the examiner's position, and submits that the drawings of the '081 provisional would have conveyed to one skilled in the art in 1995 a microtube (test unit) with the option of threadable attachment to the test unit. The examiner is directed to the Saul Declaration and Exhibits 9 and 10 thereto, which demonstrate that the term 'microtube' was commonly used by 1995 to refer to a microcentrifuge tube. Saul Declaration § 15. The depiction of the microtube test unit shown in the drawings of the '081 provisional would have conveyed to one skilled in the art in 1995 the option of using threads as a means of attaching the microtube to a test apparatus, as shown by the pages from two standard commercial catalogs (Denville Scientific Inc., *Research Products Catalog 1991*, pages 1, 2, 15 (Exhibit 9 to the Saul Declaration) and Denville Scientific Inc., *Research Products Catalog*, 1995, pages 1, 2, 16, (Exhibit 10 to the Saul Declaration), both of which were readily available and commonplace before and during 1995. It is clear from page 15 of Exhibit 9 and from page 16 of Exhibit 10 that one skilled in the art would have understood a microtube having the appearance of the microtube in the drawings of the '081 provisional to match the microtubes shown in these catalogs, which are screw cap microtubes. Accordingly, Applicant submits that the '081 provisional describes 'threads', and thus supports the limitations of claim 8, and the inclusion of 'threadable' within the means plus function recitation of claim 21. Behr et al., 27 U.S.P.Q.2d at 1407 (citing, Byrne v. Trifillis, 442 F.2d 1390, 170 USPQ 32, 34 (CCPA 1971)(“Moreover, the issue is not whether one following applicant's specification would necessarily 'produce' or select the particular combination of the counts for his own use. rather, it is whether he would necessarily recognize that such a combination was disclosed as a construction which might be selected if desired.”)

C. Claims 3, 13, and 16: buffer limitations

In keeping with the body of precedent established by the Federal Circuit in *Ralston Purina Co. v. Far-Mar-Co, Inc.*, claims 3 and 16 have been cancelled without prejudice as to the scope of subject matter encompassed by the claims from which they depend. *Ralston Purina Co. v. Far-Mar-Co, Inc.*, 772 F.2d 1570, 227 USPQ 177, 180 (Fed. Cir., 1985) (in contrast to narrowing claims that recite specific range limitations, “[t]he open ended claims, however, would be limited by what a person skilled in the art would understand to be workable.”).

Rejection under 35 U.S.C. § 112, ¶ 2

Claim 21 has been rejected under 35 U.S.C. § 112, 2nd paragraph, as being indefinite for lack of antecedent basis for the phrase “the test sample” in line 11. The rejection is overcome by adopting the examiner’s suggestion of amending the preamble to recite ‘a test sample’, which is in keeping with the language of claim 51 as it existed after entry of the preliminary amendment filed November 27, 1995 (see, applicant’s remarks in amendment of February 14, 2003, pages 5-6). The preamble of claim 21 is further amended by deleting, solely for grammatical clarity, a comma and the word ‘and’. Accordingly, the preamble to claim 21 now reads: “A transparent test unit for use in a test apparatus for the detection of a test sample, which test unit comprises:

Claim 24 has been rejected under 35 U.S.C. § 112, 2nd paragraph, as being indefinite for lack of antecedent basis for the term “said luciferase and said luciferin reagent”. The rejection is overcome by adopting the examiner’s suggestion of amending claim 24 to depend from claim 19.

Applicant respectfully requests that the rejections under 35 U.S.C. § 112, 2nd paragraph, be withdrawn.

Rejection under 35 U.S.C. § 102(a)

Claim 1 has been rejected under 35 U.S.C. § 102(a) as being anticipated by Foote et al. (WO 95/25948), which the examiner states to be available as a prior art reference under 35 U.S.C. § 102(a) as of its publication date of September 28, 1995. The rejection is respectfully traversed. Claim 1, as amended, is directed to a unit dose reagent chamber for use in a test apparatus for the detection of adenosine triphosphate (ATP), which subject matter is supported by the disclosure of provisional 60/001,081, filed July 12, 1995, and is therefore entitled to the effective filing date of July 12, 1995. *See, Saul Declaration and applicants' remarks pertaining to priority determination, above.* Applicant requests the rejection under § 102(a) be withdrawn.

Rejection under 35 U.S.C. § 103(a): Foote in view of Bernstein

Claim 2 has been rejected under 35 U.S.C. § 103(a) as not being patentable over Foote et al. (WO 95/25948) in view of Bernstein (US 4,770,853). The rejection is respectfully traversed. The recitation in claim 2 of "aluminum" finds support in the '081 provisional filed July 12, 1995. Claim 2 depends from claim 1, which as amended is also entitled to an effective filing date of July 12, 1995. Foote is only available as a prior art reference under 35 U.S.C. §103(a) as of its publication date of September 28, 1995, and thus is not available as prior art to claim 2, which is entitled to an effective filing date of July 12, 1995. *See, Saul Declaration and applicants' remarks pertaining to priority determination, above.* Bernstein, as a secondary reference, does not stand on its own to support a prima facie case of obviousness. Applicant respectfully requests that the rejection under § 103(a) be withdrawn.

Rejection under 35 U.S.C. § 103(a): Foote in view of Wood

Claims 3, 5, 6, 7, 10-14, 16, and 19 have been rejected under 35 U.S.C. § 103(a) as not.

being patentable over Foote et al. (WO 95/25948) in view of Wood (US 5,283,179). Claims 3, 11, 13, and 16 having been cancelled for the reasons discussed above, the rejection is respectfully traversed as to remaining claims 5, 6, 7, 10, 12-14, and 19, which as amended are each entitled to an effective filing date of July 12, 1995. *See, Saul Declaration and applicants' remarks pertaining to priority determination, above.* Foote is only available as a prior art reference under 35 U.S.C. §102(a) as of its publication date of September 28, 1995, and thus is not available as prior art to claims 5, 6, 7, 10-14, and 19. Wood, as a secondary reference, does not stand on its own to support a prima facie case of obviousness. Applicant respectfully requests that the rejection under § 103(a) be withdrawn.

Rejection under 35 U.S.C. § 103: Foote in view of Wood and Smola

Claims 8, 9, 17, 21, and 23 have been rejected under 35 U.S.C. § 103(a) as not being patentable over Foote et al. (WO 95/25948) in view of Wood (US 5,283,179) taken further in view of Smola et al. (US 4,004,548). The rejection is respectfully traversed.

Claims 8, 9, 17, 21, and 23, as amended, are each entitled to a priority date of July 12, 1995. *See, Saul Declaration and applicants' remarks pertaining to priority determination, above.* Foote is only available as a prior art reference under 35 U.S.C. §103(a) as of its publication date of September 28, 1995, and thus is not available as prior art to claims 8, 9, 17, 21, and 23. Wood and Smola et al., as secondary references, do not support a prima facie case of obviousness. Applicant respectfully requests that the rejection under § 103(a) be withdrawn.

Rejection under 35 U.S.C. § 103(a): Foote in view of Wood and Bernstein

Claim 15 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Foote et al. (WO 95/25948) in view of Wood (US 5,283,179), taken further in view of Bernstein (US

4,770,853). The rejection is respectfully traversed.

Claim 15, as amended, is entitled to an effective filing date of July 12, 1995. *See, Saul Declaration and applicants' remarks pertaining to priority determination, above.* Foote is only available as a prior art reference under 35 U.S.C. §103(a) as of its publication date of September 28, 1995, and thus is not available as prior art to claim 15. Wood and Bernstein, as secondary references, do not support a prima facie case of obviousness. Applicant respectfully requests that the rejection under § 103(a) be withdrawn.

Rejection under 35 U.S.C. § 103(a): Foote in view of Wood, Smola, and Bernstein

Claim 22 has been rejected under 35 U.S.C. § 103(a) as not being patentable over Foote et al. (WO 95/25948) in view of Wood (US 5,283,179) and Smola et al. (US 4,004,548), taken further in view of Bernstein (US 4,770,853). The rejection is respectfully traversed.

Claim 22, as it depends from claim 21 as amended, is entitled to an effective filing date of July 12, 1995. *See, Saul Declaration and applicants' remarks pertaining to priority determination, above.* Foote is only available as a prior art reference under 35 U.S.C. §103(a) as of its publication date of September 28, 1995, and thus is not available as prior art to claim 22. Wood, Smola, and Bernstein, as secondary references, do not support a prima facie case of obviousness. Applicant respectfully requests that the rejection under § 103(a) be withdrawn.

Rejection under 35 U.S.C. § 103(a): Foote in view of Wood and Rich

Claim 24 has been rejected under 35 U.S.C. § 103(a) as not being patentable over Foote et al. (WO 95/25948) in view of Wood (US 5,283,179, taken further in view of Rich (US 3,666,631). The rejection is respectfully traversed.

Claim 24, as it depends from claim 21 as amended, is entitled to an effective filing date of

July 12, 1995. *See, Saul Declaration and applicants' remarks pertaining to priority determination, above.* Foote is only available as a prior art reference under 35 U.S.C. §103(a) as of its publication date of September 28, 1995, and thus is not available as prior art to claim 24. Wood and Rich, as secondary references, do not support a prima facie case of obviousness. Applicant respectfully requests that the rejection under § 103(a) be withdrawn.

Rejection under 35 U.S.C. § 103(a): Foote in view of Wood, Smola, and Rich

Claims 25 and 26 have been rejected under 35 U.S.C. § 103(a) as not being patentable over Foote et al. (WO 95/25948) in view of Wood (US 5,283,179) and Smola et al. (US 4,004,548), taken further in view of Rich (US 3,666,631). The rejection is respectfully traversed.

Claims 25 and 26, as it depends from claim 21 as amended, is entitled to an effective filing date of July 12, 1995. *See, Saul Declaration and applicants' remarks pertaining to priority determination, above.* Foote is only available as a prior art reference under 35 U.S.C. §103(a) as of its publication date of September 28, 1995, and thus is not available as prior art to claims 25 and 26. Wood and Rich, as secondary references, do not support a prima facie case of obviousness. Applicant respectfully requests that the rejection under § 103(a) be withdrawn.

Rejection under 35 U.S.C. § 103(a): Foote in view of Wood and Abbas

Claim 20 has been rejected under 35 U.S.C. § 103(a) as not being patentable over Foote et al. (WO 95/25948) in view of Wood (US 5,283,179), taken further in view of Abbas (US 5,223,402). Claim 20 having been cancelled, applicant requests that the rejection be withdrawn as moot.

Rejection under 35 U.S.C. § 103(a): Matsumoto in view of Smola

Claims 21 and 25 have been rejected under 35 U.S.C. § 103(a) as not being patentable

over Matsumoto et al. (JP 07-59555) in view of Smola et al. (US 4,004,548). The rejection is respectfully traversed.

Applicants respectfully submit that claims 21 and 25 are directed to a test unit that is detachably securable to a test apparatus. Matsumoto et al. does not disclose explicitly nor render obvious, a *test unit* that can be *detachably secured* to a test apparatus. It follows, then, that one skilled in the art would not be motivated to consult Smola et al. for a solution to the problem of how to detachably secure a test unit microtube to a test apparatus. *See, Smola et al., col. 6, lines 49-52 (“..., the reservoir portion 22a is firmly secured . . .”)* (emphasis added). Applicant respectfully requests that the rejection under § 103(a) be withdrawn.

(In the event that the examiner is not disposed to withdraw the instant rejection, applicant requests that the examiner articulate clearly the structures in Matsumoto that are considered to correspond with applicant's detachable 'test unit' and applicant's 'test apparatus.' In actuality, Matsumoto et al. discloses the "member (7)" to be "a collector plug 7." *Matsumoto et al. (see, certified translation, page 3, line 21).* A 'collector plug' is not a 'test apparatus' by any stretch of the imagination.)

Rejection under 35 U.S.C. § 103(a): Matsumoto in view of Smola and Bernstein

Claim 22 has been rejected under 35 U.S.C. § 103(a) as not being patentable over Matsumoto et al. (JP 07-59555) in view of Smola et al. (US 4,004,548), taken further in view of Bernstein (US 4,770,853). The rejection is respectfully traversed. Applicant respectfully submits that claim 22 depends from claim 21, and is therefore distinguished from Matsumoto and Smola on the same grounds used to overcome the rejection of claims 21 and 25 under § 103(a), above (which grounds are hereby incorporated by reference). Consistent with such grounds,

Bernstein neither discloses explicitly nor renders obvious a *test unit* that can be *detachably secured* to a test apparatus. It follows, then, that one skilled in the art would not be motivated to consult Smola et al. for a solution to the problem of how to detachably secure a test unit microtube to a test apparatus. *Smola et al.*, col. 6, lines 49-52 (" . . . , the reservoir portion 22a is *firmly secured . . .*") (emphasis added). Applicant respectfully requests that the rejection under § 103(a) be withdrawn.

CONCLUSION

The present Amendment is being filed within six months of the mailing date of the Office Action. A Petition for Extension of Time Under 37 C.F.R. 1.136(a) for a three-month extension of time, is submitted herewith. Please charge any outstanding fees or overpayments to Deposit Account No. 50-1895, Ref. No. 0656-008US6.

Respectfully submitted,

Date: March 25, 2004



Leslie Meyer-Leon
Reg. No. 37,381

IP LEGAL STRATEGIES GROUP P.C.
P.O. Box 1210, 1480 Falmouth Road
Centerville, MA 02632-1210
Telephone: 508-790-9299
Facsimile: 508-790-1955

Enclosures: Petition for Extension of Time (Three months)
Fee transmittal
Supplemental Reissue Declaration
Declaration of Steven J. Saul with Exhibits 1-10 thereto
Exhibit A
Express Mail Certificate
Postcard